



#8

## PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Seema Garde, et al.  
For : **PHARMACEUTICAL PREPARATIONS AND  
METHODS FOR INHIBITING TUMORS**  
Serial No. : 09/977,406  
Filed : October 15, 2001  
Art Unit : 1615  
Attorney Docket No. : CLW 2 0147

### PRELIMINARY AMENDMENT

Assistant Commissioner of Patents  
Washington, D.C. 20231

Dear Sir:

Prior to substantive examination of the captioned application, please amend the application as follows:

#### In the Claims:

Please add claims 96-183 as follow:

96. The use of rHuPSP94 as set forth in SEQ ID NO: 2 according to claim 5 wherein rHuPSP94 is used in a dosage range from about 10 micrograms/kg/day to about 4 milligrams/kg/day.

#### CERTIFICATE OF MAILING

I hereby certify that this **PRELIMINARY AMENDMENT** and all other documents indicated therein as being enclosed are being deposited with the United States Postal Service in an envelope with sufficient postage for First Class Mail on the date indicated below and is addressed to the Assistant Commissioner for Patents, Washington, D. C. 20231.

Mary M. Schriener  
Mary M. Schriener

March 19, 2002  
Date

09977406-032802

97. The use of rHuPSP94 as set forth in SEQ ID NO: 2 according to claim 5 wherein rHuPSP94 is used in a dosage range from about 500 picograms/kg/day to about 1 milligram/kg/day.

98. The use of rHuPSP94 as set forth in SEQ ID NO: 2 according to claim 5 wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 10 micrograms/kg/day.

99. The use of rHuPSP94 as set forth in SEQ ID NO: 2 according to claim 5 wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 500 nanograms/kg/day.

100. The use of a polypeptide according to claim 5 wherein said polypeptide is selected from the group consisting of the decapeptide as set forth in SEQ ID NO: 3, the polypeptide as set forth in SEQ ID NO: 4, the polypeptide as set forth in SEQ ID NO: 5, the polypeptide as set forth in SEQ ID NO: 6, and mixtures thereof wherein said polypeptide is used in a dosage range from about 100 nanograms/kg/day to about 4 milligrams/kg/day.

101. The use of a polypeptide according to claim 5 wherein said polypeptide is used with an anticancer drug.

102. The use of a polypeptide according to claim 101 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

103. The use of a polypeptide according to claim 5 wherein said polypeptide is used with a pharmaceutically acceptable carrier.

2025-09-04 14:06:03

104. The use of a polypeptide according to claim 101 wherein said polypeptide is used with a pharmaceutically acceptable carrier.

105. The use of a polypeptide according to claim 5 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

106. The use of a polypeptide according to claim 101 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

107. The use of a polypeptide according to claim 103 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

108. The use of a polypeptide according to claim 104 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

109. The use of a polypeptide analog according to claim 20 wherein said polypeptide analog is used with an anticancer drug.

110. The use of a polypeptide analog according to claim 109, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

111. The use of a polypeptide analog according to claim 20 wherein said polypeptide analog is used with a pharmaceutically acceptable carrier.

2009-03-04 14:06:50

112. The use of a polypeptide analog according to claim 109 wherein said polypeptide analog is used with a pharmaceutically acceptable carrier.

113. The use of a polypeptide analog according to claim 20, wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

114. The use of a polypeptide analog according to claim 109 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

115. The use of a polypeptide analog according to claim 111 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

116. The use of a polypeptide analog according to claim 112 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

117. The method according to claim 30 wherein rHuPSP94 (SEQ ID NO: 2) is administered in a dosage range from about 10 micrograms/kg/day to about 4 milligrams/kg/day.

118. The method according to claim 30 wherein rHuPSP94 (SEQ ID NO: 2) is administered in a dosage range from about 25 picograms/kg/day to about 1 milligram/kg/day.

119. The method according to claim 30 wherein human rHuPSP94 (SEQ ID NO: 2) is administered in a dosage range from about 5 nanograms/kg/day to about 10 micrograms/kg/day.

200907106-033600

120. The method according to claim 30 wherein said polypeptide is selected from the group consisting of the decapeptide as set forth in SEQ ID NO: 3, the polypeptide as set forth in SEQ ID NO: 4, the polypeptide as set forth in SEQ ID NO: 5, the polypeptide as set forth in SEQ ID NO: 6, and mixtures thereof, wherein said polypeptide is used in a dosage range from about 100 nanograms/kg/day to about 4 milligrams/kg/day.

121. The method according to claim 30 wherein said polypeptide is used with an anticancer drug.

122. The method of claim 121 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

123. The method according to claim 30 wherein said polypeptide is used with a pharmaceutically acceptable carrier.

124. The method according to claim 121 wherein said polypeptide is used with a pharmaceutically acceptable carrier.

125. The method according to claim 30 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

126. The method according to claim 121 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

2025090424660

127. The method according to claim 123 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

128. The method according to claim 124 wherein said polypeptide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide.

129. The method according to claim 44 wherein said vector is used with an anticancer drug.

130. The method according to claim 129, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

131. The method according to claim 44 wherein said vector is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said vector.

132. The method according to claim 129 wherein said vector is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said vector.

133. The method according to claim 50 wherein said polynucleotide is used with an anticancer drug.

134. The method according to claim 133, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

203230-9042660

135. The method according to claim 50 wherein said polynucleotide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polynucleotide.

136. The method according to claim 133 wherein said polynucleotide is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polynucleotide.

137. The method according to claim 56 wherein said polypeptide analog is used with an anticancer drug.

138. The method according to claim 137, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

139. The method according to claim 56, wherein said polypeptide analog is used with a pharmaceutically acceptable carrier.

140. The method according to claim 137, wherein said polypeptide analog is used with a pharmaceutically acceptable carrier.

141. The method according to claim 56, wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

142. The method according to claim 137 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

09977406-032803

143. The method according to claim 139 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

144. The method according to claim 140 wherein said polypeptide analog is used with a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of said polypeptide analog.

145. A pharmaceutical composition according to claim 66, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 10 micrograms/kg/day to about 4 milligrams/kg/day.

146. A pharmaceutical composition according to claim 67, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 10 micrograms/kg/day to about 4 milligrams/kg/day.

147. A pharmaceutical composition according to claim 68, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 10 micrograms/kg/day to about 4 milligrams/kg/day.

148. A pharmaceutical composition as in claim 66, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 500 picograms/kg/day to about 1 milligram/kg/day.

149. A pharmaceutical composition as in claim 67, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 500 picograms/kg/day to about 1 milligram/kg/day.

203220-9042660



150. A pharmaceutical composition as in claim 68, wherein rHuPSP94 (SEQ ID NO: 2) is used in a dosage range from about 500 picograms/kg/day to about 1 milligram/kg/day.

151. A pharmaceutical composition as in claim 66, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 10 micrograms/kg/day.

152. A pharmaceutical composition as in claim 67, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 10 micrograms/kg/day.

153. A pharmaceutical composition as in claim 68, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 10 micrograms/kg/day.

154. A pharmaceutical composition as in claim 66, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 500 nanograms/kg/day.

155. A pharmaceutical composition as in claim 67, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 500 nanograms/kg/day.

156. A pharmaceutical composition as in claim 68, wherein rHuPSP94 is used in a dosage range from about 5 nanograms/kg/day to about 500 nanograms/kg/day.

157. A pharmaceutical composition as in claim 66, wherein said polypeptide is selected from the group consisting of the decapeptide as set forth in SEQ ID NO: 3, the polypeptide as set forth in SEQ ID NO: 4, the polypeptide as set forth in SEQ ID NO: 5, the polypeptide as set forth in SEQ ID NO: 6 and mixture(s) thereof, wherein said polypeptide is used in a dosage range from about 100 nanograms/kg/day to about 4 milligrams/kg/day.

0977406-032302

158. A pharmaceutical composition as in claim 67, wherein said polypeptide is selected from the group consisting of the decapeptide as set forth in SEQ ID NO: 3, the polypeptide as set forth in SEQ ID NO: 4, the polypeptide as set forth in SEQ ID NO: 5, the polypeptide as set forth in SEQ ID NO:6 and mixture(s) thereof, wherein said polypeptide is used in a dosage range from about 100 nanograms/kg/day to about 4 milligrams/kg/day.

159. A pharmaceutical composition as in claim 68, wherein said polypeptide is selected from the group consisting of the decapeptide as set forth in SEQ ID NO: 3, the polypeptide as set forth in SEQ ID NO: 4, the polypeptide as set forth in SEQ ID NO: 5, the polypeptide as set forth in SEQ ID NO:6 and mixture(s) thereof, wherein said polypeptide is used in a dosage range from about 100 nanograms/kg/day to about 4 milligrams/kg/day.

160. A pharmaceutical composition according to claim 68 further comprising an anticancer drug.

161. A pharmaceutical composition according to claim 67, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

162. A pharmaceutical composition according to claim 74, wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

163. A pharmaceutical composition according to claim 160 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

202509040600

164. A pharmaceutical composition as in claim 66, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

165. A pharmaceutical composition as in claim 67, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

166. A pharmaceutical composition as in claim 68, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

167. A pharmaceutical composition as in claim 74, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

168. A pharmaceutical composition as in claim 160, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

169. A pharmaceutical composition according to claim 78 further comprising an anticancer drug.

170. A pharmaceutical composition according to claim 169 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

171. A pharmaceutical composition according to claim 79 further comprising an anticancer drug.

05977406-036802

172. A pharmaceutical composition according to claim 171 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

173. A pharmaceutical composition according to claim 80 further comprising an anticancer drug.

174. A pharmaceutical composition according to claim 173 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

175. A pharmaceutical composition according to claim 86, further comprising an anticancer drug.

176. A pharmaceutical composition according to claim 175 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

177. A pharmaceutical composition according to claim 85 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

178. A pharmaceutical composition according to claim 87 wherein said anticancer drug is selected from the group consisting of mitomycin, idarubicin, cisplatin, 5-fluoro-uracil, methotrexate, adriamycin, daunomycin, taxol, taxol derivative, and mixtures thereof.

179. A pharmaceutical composition according to claim 84 further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

2025-09-04 14:06:09

180. A pharmaceutical composition according to claim 85 further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

181. A pharmaceutical composition according to claim 86, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

182. A pharmaceutical composition according to claim 87, further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

183. A pharmaceutical composition according to claim 175 further comprising a time-release means selected from the group consisting of liposomes and polysaccharides for effecting continual dosing of the composition.

Respectfully submitted,

FAY, SHARPE, FAGAN,  
MINNICH & McKEE, LLP



Timothy E. Nauman  
Reg. No. 32,283  
Brian G. Bembenick  
Reg. No. 41,463  
1100 Superior Avenue, 7th Floor  
Cleveland, Ohio 44114-2518  
(216) 861-5582